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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,519	11/01/1999	SHIH CHUNG	AH0948Q	8808

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PATENT DEPARTMENT
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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/431,519	CHUNG ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-49,51-65 and 67-93* is/are pending in the application.

4a) Of the above claim(s) *78-93* is/are withdrawn from consideration.

5)☐ Claim(s) *76 and 77* is/are allowed.

6)☒ Claim(s) *43- 49,51-54,56-58,62-65,67-69 & 71-75* is/are rejected.

7)☒ Claim(s) *55,59-61,70* is/are objected to.

8)☒ Claim(s) *57-65 and 67-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 78-93 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention , there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/19/00

Claim Rejections - 35 USC § 103

Claims 43- 49,51-54,56-58,62-65,67-69 & 71-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over DEASY 4874612 in view of SCHAAF 4758435.

DEASY clearly presents the same anabolic agent, exemplified with estradiol, but inclusive of the instant zearanol (col. 3, lines 35-43) in 2 formulations delivered as one implant, which vary in the release agent (col. 4, lines 10-16, 30-59), & with presence or absence of filler/diluent (col. 3, lines 10-15). Note that The instant open language does not exclude the unspecified controlled release agent of claims 43, 75 & 76, nor are the ratios or concentrations of ingredients specified. The ratio of the 2 components is shown in the examples, & is within the instant ranges.

Absent any limitation or quantification to the terms “immediate release” & “controlled release” these 2 forms are seen as provided by Deasy. Increased molecular weight delays degradation & release of active, as does the ratio of poly-lactic to glycolic acid copolymers (col. 2, lines 26-58) & so the duration of release can be varied as

desired. However , there is also known to be a burst effect (col. 1, bottom, 2.,top) such that immediate release and controlled release occur from the same implant.See Schaff, col. 2, lines 18-30. In fact, while controlled release is desired, coating the implant with the same drug as of the controlled release lactide/gycolide formulation imparts immediate relaease(col. 1, lines 26-33). Thus, one in the art would find it obvious & within their purview to select zeranol from the few Deasy drugs, & aply the 2 formulations as an implant, coated with zeranol if desiring to decrease the time before effectiveness of increasing growth & feed efficiency results as expected from the findings at the 2007 supreme court decision in KSR V TELEFLEX @ 82 USPQ 2d @ 1385. The selection of zeranol, & testing of efficacy with the use of Deasy's 2 forms of formulations as an implant would be well within the ability of the artisan to test with expectation of success.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an anabolic implant to use one of Deasy modified with a coating of the drug, in order to provide acceptable results as soon as possible. The selection of each ingredient is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.

There is no unobvious and/or unexpected results obtained since the prior art is well aware of the use of zearlone for enhancement , lactose as fileer or diluent, & copolymers of lactic & glycolic acid as controllers of release,and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

Claims 76,77 are allowed.

Applicant's arguments filed 12/26/07 have been fully considered but they are not persuasive. Applicant argues the text does not recite Ralgro as both immediate & controlled release, & on this basis the rejection over the specification is withdrawn. Claims 76 & 77 are not seen as anticipated or suggested by the prior art of record, but the prior rejections in consideration of the findings in KSR mandate reconsideration of the references of record. Given KSR, the concentrations of zeralone & ratios as in claims 59-61 would , if added to claim 58, provide a basis for allowance as non-obvious over the references of record..

However, claims 89-93 are not seen as warranting rejoining as the method here requires 2 different compositions, as opposed to the examined single composition of 2 combined formulations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/
Primary Examiner, Art Unit 1615